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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,910	09/09/2003	Kenichi Chiba	2003946-0056 (ANDI/CIP)	5169

24280 7590 07/11/2007  
CHOATE, HALL & STEWART LLP  
TWO INTERNATIONAL PLACE  
BOSTON, MA 02110

EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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07/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,910	<b>Applicant(s)</b> CHIBA ET AL.	
	<b>Examiner</b> Taylor Victor Oh	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24,27-31,33,36,38-40,42,43 and 45-66 is/are pending in the application.
- 4a) Of the above claim(s) 36,38-40,42,43,45-61 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24,27-31,33,62-63,65-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The Status of Claims:

Claims 1-24,27-31,33,36,38-40,42-43,45-66 are pending.

Claims 1-24,27-31,33,62-63, and 65-66 are rejected.

Claims 36, 38-40,42-43,45-61,64 are withdrawn from consideration.

DETAILED ACTION

1. Claims 1-24,27-31,33,62-63, and 65-66 are under consideration in this Office Action.

Priority

2. It is noted that the application is a CIP of PCT/US03/07377 (03/07/2003) which claims benefit of 60/362,883 (03/08/2002 and claims benefit of 60/380,711 (05/14/2002).

Drawings

3. None.

***Election/Restrictions***

Applicant's election without traverse of Group IV (claims 1-24,27-31,33,62-63, and 65-66 ) on 4/23/07 is acknowledged.

Claims 36, 38-40,42-43,45-61,64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups I-III and V, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 -20 ,21-24, 27-31, 33, and 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2 the terms " heteroaliphatic ,heteroalicyclic, heteroary, heteroaryl moiety, a protecting group " are recited. These are vague and indefinite because those terms need to be defined clearly for how many carbon and hetero atom members of the ring system are present in the ring.

In claims 1,2 the phrase "a protecting group " is recited. This is vague and indefinite because this needs to be defined clearly for what kind of the " protecting group " are present and used in the claim.

In claim 1, 14, the phrase "a saturated or unsaturated cyclic ring containing 1 to 4 carbon atoms" is recited. This is vague and indefinite because the term "containing" would mean that there are additional substituents present in the saturated or unsaturated cyclic ring; the skilled artisan in the art is unable to figure out what they are other than what is described in the claim.

In claims 1, 21-24, 27-31, 33, and 62-63, the phrase "acceptable derivative" is recited. This is vague and indefinite because the specification does not elaborate what is meant by the terms "acceptable derivative" in the claims.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

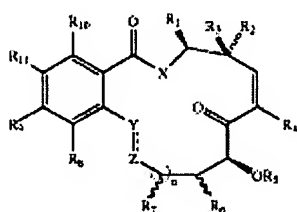
Claims 1-24, 27-31, 33, 62-63, and 65-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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22,40,43,66, and 81 of copending Application No. 10/507,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are overlapped in a genus and a species relationship.

In the instant claim 1, the following limitations are described as below:

A pharmaceutical composition for systemic administration comprising a compound having the structure:



(a)

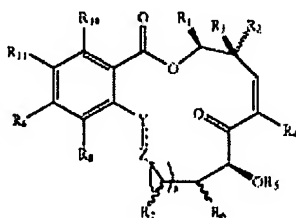
or pharmaceutically acceptable derivative thereof;

R1-R11 are defined; X is equal to oxygen; Y

and Z are carbon.

However, the instant invention differs from the copending application in the followings:

1. A compound having the structure:



(b)

X is absent or is O, NH, N-alkyl, CH<sub>2</sub> or S;

Y is CHR<sub>17</sub>, O, C=O, CR<sub>17</sub> or NR<sub>17</sub>; and Z is CHR<sub>18</sub>, O, C=O, CR<sub>18</sub> or NR<sub>18</sub>, wherein each occurrence of R<sub>17</sub>

R1-R11 are defined;


The limitations of the co-pending application is broader than the instant invention. Therefore, they are in a genus and a species relationship. Therefore, it

would have been obvious to the skilled artisan in the art to be motivated to emphasize the species from the genus of the formula.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Taylor Victor Oh, MSD, LAC  
Primary Examiner  
Art Unit: 1625

7/6/07